MDS Nordion
Science Advancing Health

K011246

510(k) Summary

1.1 Submitter:

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CANADA

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Contact Person:

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Vice President
Quality & Regulatory Affairs
447 March Road
Kanata, Ontario K2K 1X8
CANADA

1.2 Device Manufacturer:

MDS Nordion AB
Box 1704
SE-75147 Uppsala
SWEDEN

1.3 Device Name: DCM

1.4 Classification Name: Medical Charged-Particle Radiation Therapy System (892.5050)

1.5 Common or Usual Name: Radiation Therapy Treatment Planning System

1.6 Legally Marketed Predicate Device:

Helax-TMS v 5.0 (K993766)

1.7 Description of Dose Calculation Module (DCM):

DCM 1.0 is intended for calculations of dose plans and communication with a Treatment Planning System based on DICOM objects. The calculation core of DCM is a subset of Helax-TMS, and generates the same calculation results as Helax-TMS.

1.8 Intended use of DCM:

DCM is a three-dimensional radiotherapy dose engine for radiation dose planning of patients undergoing external beam treatment in the oncology clinic.

Based on quality assured radiation therapy input data Dose Calculation Module (DCM) is used to plan radiation treatment with:

- Linear accelerators with X-ray energies from 4 to 50MV
- Cobalt-60 units

DCM will calculate dose for 3D radiotherapy treatment approaches of combined modality plans, asymmetric and non-coplanar fields; total body irradiation; multi-leaf collimators; motorized and dynamic wedges; customized blocking.

Note: This intended use is a direct subset of the Intended Use of the predicate device, Helax-TMS which reads as follows:

Helax-TMS is a 3D radiotherapy treatment planning system for radiation dose planning, but not treatment, of patients undergoing external beam or Brachytherapy treatment in the Oncology clinic. The system is designed to lead the user through a logical flow planning process.

Based on quality assured radiation therapy input data Helax-TMS is used to plan radiation treatments with:

(i) linear accelerators with X-ray energies from 4 to 50 MV and electron energies from 4 to 50 MeV as well as cobalt-60 units. Helax-TMS will plan 3D radiotherapy treatment approaches of combined modality plans, asymmetric and non-coplanar fields; total body irradiation; multi-leaf collimators; motorize and dynamic wedges; customised blocking; compensating filters; and bolus.

(ii) Brachytherapy units for patients undergoing interstitial or intracavitary treatment in the Oncology clinic.

Export capabilities exists as part of Helax-TMS to verify beam and patient data, dose planning results, and provide on-line information to block-cutting and milling machines, multi-leaf collimator control units, as well as record and verify systems.

1.9 Technological Characteristics

DCM version 1.0 is the dose calculation engine from the already cleared TMS version 5.0, Radiation Therapy Treatment Planning System.

These modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device.

2.0 Safety and Effectiveness

DCM 1.0 is a subset of already cleared TMS 5.0, and does not introduce any new safety or effectiveness issues.

E.S. Martell
Vice President
Quality and Regulatory Affairs

17 May 2001
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2001

Mr. E. S. Martell
Vice President, Quality & Regulatory Affairs
MDS Nordion, Inc.
447 March Road
KANATA ONTARIO
CANADA K2K 1X8

Re: K011246
Dose Calculation Module (DCM) v. 1.0
Dated: April 19, 2001
Received: April 23, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 MUJ

Dear Mr. Martell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Section 10.0

Indications for Use

510 (k) Number: K011246

Device Name: DCM version 1.0

Indications For Use:

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Based on quality assured radiation therapy input data Dose Calculation Module is used to plan radiation treatment with:

- Linear accelerators with X-ray energies from 4 to 50MV
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DCM will calculate dose for 3D radiotherapy treatment approaches of combined modality plans, asymmetric and non-coplanar fields; total body irradiation; multi-leaf collimators; motorized and dynamic wedges; customized blocking.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011246

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(PER 21 CFR 801.109)

(Optional Format 1-2-96)